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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/944,739	09/14/92	KYLE	14761211

SC

E. ANTHONY FIGG
ROTHWELL, FIGG, ERNST & KURZ
555 13TH STREET, N.W., STE. 701-E
WASHINGTON, D.C. 20004

12M2/1112

TORIYAN, K
EXAMINER

ART UNIT
1205

24
11/12/93

PAPER NUMBER

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

8/13/93

This application has been examined Responsive to communication filed on 7/27/93 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892. 2. Notice re Patent Drawing, PTO-848.
3. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of Informal Patent Application, Form PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474. 6.

Part II SUMMARY OF ACTION

1. Claims 67 - 94 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 1 - 66 have been cancelled.

3. Claims _____ are allowed.

4. Claims 67 - 94 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-848).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed on _____, has been approved. disapproved (see explanation).

12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

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Claims 67-94 are pending in this application.

The amendment received on July 27, 1993 has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

The limitations of the claims drawn to requiring the fatty acids to be in triglyceride form and "substantially free" of eicosapantaenoic acid (EPA) were not disclosed in the original specification and thus constitute new matter.

Claims 67-92, 94 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which

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the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 67-94 are rejected under 35 U.S.C. § 103 as being unpatentable over Japanese Patent Application #196,255(AL) and PCT Application #WO89/00606 (AL') in view of Clandinin et al. (AA) and Traitler et al. (AI).

The claims appear to be drawn to processes, compositions and nutritional supplements for enriching infant formulas or milk by adding polyunsaturated fatty acids from microbial, plant and fish oil sources. JPA #196,255 teaches the process of adding microbial oils produced by Mortierella bacteria to supplement milk for infants (see pages 4-5 and 7-8). The microbial oils contain polyunsaturated fatty acids such as gamma-linoleic acid (GLA), arachidonic acid (ARA) and eicosapentaenoic acid (EPA) (see pages 4-5 and 7-8). PCT Application #WO89/00606 teaches the supplementation of infant and adult nutritional formulas with microbial oils containing the polyunsaturated fatty acids docosahexaenoic acid (DHA) and EPA (see pages 3-5). The microbial oils are obtained from the fungi, Pythium and from the microalgae, Nitzschia and Cryptocodium (see page 5). The claimed subject matter differs from the primary references in

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claiming the addition of GLA obtained from plant and fish oils. To supplement infant formulas with GLA obtained from plant and fish oils would have been obvious in view of Clandinin et al. and Traitler et al. Clandinin et al. teaches the addition of fatty acids from fish oil to infant formula (see column 2, line 61-column 3, line 8 and column 6, line 8 - column 7, line 17). Traitler et al. teach the addition of GLA to infant formula wherein the GLA is obtained from black current oil (see column 3, lines 21-61). The choice of various ratios for the ingredients is deemed to be nothing more than the optimization of the composition which is within the skill of the artisan. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. The remaining references listed on the enclosed PTO-1449 are cited to show the state of the art.

The applicant's remarks have been considered but are unpersuasive. Applicant's remarks and the Kyle declaration are drawn to rebutting the prior art in view of new claims 67-94 which contain limitations which are new matter. Thus the remarks and declaration are not persuasive of patentability of subject matter which was disclosed in the original specification.

No claims are allowed.

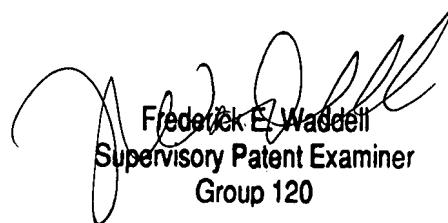
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Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kimberly Jordan whose telephone number is (703) 308-4611.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Frederick E. Waddell
Supervisory Patent Examiner
Group 120

JORDAN:tce KJN
November 03, 1993